## UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS

UNITED STATES

v.

No. 1:21-cr-10256-IT

KINGSLEY R. CHIN, *Defendant*.

# DEFENDANT CHIN'S OPPOSITION TO GOVERNMENT'S MOTION IN LIMINE TO PRECLUDE EVIDENCE OR ARGUMENT CONCERNING LACK OF PATIENT HARM OR ABSENCE OF MEDICALLY UNNECESSARY SERVICES

Defendant Kingsley Chin respectfully opposes the government's motion *in limine* that attempts to preclude him from using evidence or making arguments concerning the lack of patient harm or the absence of medically unnecessary services.

## **Preliminary Statement**

While the government may be correct that it has no burden to prove that Dr. Chin caused harm to patients or caused medically unnecessary services, the government's motion takes an erroneous leap from that position to the scope of admissible evidence. The government argues that Dr. Chin cannot rely on circumstances surrounding the consulting program at issue, even (1) to attack the credibility of witnesses (including doctors who may testify that they accepted bribes to use SpineFrontier products in surgeries for their patients), (2) to rebut accusations of a "sham" consulting "program," (3) to rebut evidence of alleged willfulness, or (4) to rebut efforts by the government to establish a conspiratorial intent to induce improperly purchases of products. The government misplaces reliance on case law that fails to support its overaggressive position.

At most, after the completion of the government's case-in-chief or at the charge conference, this Court will be able to address whether the government is entitled to pertinent jury instructions.

For example, the government could have requested an instruction that it need not prove patient harm or medically unnecessary services. Or perhaps the government will be entitled to a limiting instruction that evidence of benefits to patients and improvements to the treatment of them are relevant only to the issues of credibility of witnesses, or whether the government has met its burden of proving that Dr. Chin intentionally induced a surgeon to do business with SpineFrontier or whether he acted knowingly or willfully.

As described below, the case law on which the government relies does not, however, support a pretrial parsing apart of evidence or argument about surrounding circumstances on issues of credibility or *mens rea*, which need to be assessed on the record that develops at trial. Importantly, our adversarial system allows defendants to challenge the accusations against them and, here, to demonstrate that the consulting program was far from the "sham" that the Superseding Indictment expressly alleges by showing how the program served lawful benefits for patients. The evidence also tends to show Dr. Chin's good faith. On the other hand, preclusion of such evidence could mislead the jury to believe that the products were used for medically unnecessary purposes or that patients were harmed. Accordingly, this Court should deny the government's motion or at least defer it until the appropriate time during the trial.

#### **Background**

Evidence at trial will show that, with respect to SpineFrontier's consulting program, Dr. Chin acted in good faith, with the goal of innovation for SpineFrontier's industry-leading products that, in turn, would improve care for patients. Recently, as a newly-configured prosecution team interacted with witnesses and reviewed reports of witness statements, the government dismissed all charges against SpineFrontier and three of the substantive counts charging Dr. Chin with violations of the Anti-Kickback Statute. In doing so, the government dropped its accusations about more than 75% of the payments that appeared in the original charges.

Nevertheless, the Superseding Indictment that the Grand Jury returned still expressly charges that the defendants put in place and used a "sham" consulting "program." As discussed in Dr. Chin's motion for a bill of particulars, the government has declined to confirm that its conspiracy theory is limited to conspiring to make payments to the three surgeons who are the subjects of the Superseding Indictment's counts for violations of the AKS. Paragraph 23 of the Superseding Indictment, for example, charges that defendants are responsible for directing bribes to surgeons "pursuant to a sham consulting program." Paragraph 24 also refers to "SPINEFRONTIER's sham consulting program." In Paragraph 26, the Superseding Indictment alleges that Dr. Chin and Mr. Humad "designed" the consulting program for the purpose of making "bribes" to surgeons. In Paragraph 31(i), the Indictment alleges the creation of records and documents, "including purportedly legitimate contracts, designed to make the sham consulting program appear legitimate." The Indictment also impugns the entirety of the consulting program by alleging that Impartial Medical Experts, LLC, the entity through which all consulting payments were made after a particular period, not just payments to alleged co-conspirators, "purported to manage the process pursuant to which SPINEFRONTIER's surgeons submitted hours and received payments from or on behalf of SPINEFRONTIER for purported consulting." (Indictment ¶ 4 (emphases added).) The government now argues that Dr. Chin cannot rebut these accusations or show that the program supported proper consulting work, or even that he lacked the requisite *mens* rea, for the jury to understand that the program functioned properly.

In the context of an allegedly "sham" consulting program and allegations of willfulness, the Superseding Indictment places at issue whether Dr. Chin interacted with SpineFrontier's consulting program with a bad purpose to violate the law, a proper purpose to innovate for the benefit of patients, or some other innocent purpose. The pertinent provisions of the Anti-Kickback Statute invoked in the remaining three substantive counts in the Indictment provide:

Whoever **knowingly and willfully** offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person **to induce such person**—

(B) to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,

shall be guilty of a felony and upon conviction thereof, shall be fined not more than \$100,000 or imprisoned for not more than 10 years, or both.

42 U.S.C. § 1320a-7b(b)(2) (emphases added). The Superseding Indictment also charges a conspiracy, placing at issue whether Dr. Chin and his alleged co-conspirators shared a common unlawful purpose and corrupt intent to conspire through a "sham" consulting program, in violation of 18 U.S.C. § 371.

Despite these matters placed at issue for trial by the Superseding Indictment, the government seeks broad preclusion of evidence and argument, including prohibitions that could limit the jury's ability to consider whether the consulting program existed or continued in good faith because of its positive impact on patients and an intent to improve medical care. To be clear, Dr. Chin does not seek to conduct a mini-trial over harm or benefits to patients, or whether any physicians could disagree about the best form of treatment. Neither the government nor Dr. Chin has identified a retained expert witness to opine about the quality or consequences of medical care or necessity. Nevertheless, a jury should be able to assess (1) the credibility of any government witnesses who criticizes the consulting program as a sham or designed for illicit purposes or the like, or (2) whether Dr. Chin lacked criminal culpability and caused payments for a purpose other than for inducing purchases, at least in part because physicians chose SpineFrontier's products as the best choice for their patients, and why.

#### Discussion

Dr. Chin Is Entitled to Attack the Credibility of Government Witnesses, and to Rebut the Government's Theories of Willfulness and Efforts to Prove Payments for Inducing Purchases, Including Through References to Reasons for Believing in the Positive Impacts on and Proper Care for Patients.

The government seeks to cripple Dr. Chin's ability to rebut express accusations of a "sham" consulting program that appear in the Superseding Indictment, and to preclude an attack on the credibility of government witnesses or otherwise challenge any proof of Dr. Chin's alleged criminal intent. Specifically, the government attempts in this motion to block evidence and argument about the positive aspects of the consulting program known to Dr. Chin that naturally contributed to a belief in its propriety. Proving a violation of the Anti-Kickback Statute requires proof beyond a reasonable doubt that defendants acted knowingly and willfully. See 42 U.S.C. § 1320a-7b(b)(2). Willfulness is to be determined based on "all the surrounding circumstances." Rutkin v. United States, 343 U.S. 130, 135 (1952); see United States v. Mena, 933 F.2d 19, 25 n.5 (1st Cir. 1991) (allowing evidence of after-the-fact acts as having "obvious evidentiary significance in establishing what happened during" the event at issue because a defendant's intent can be inferred "in light of all the surrounding circumstances" (citation omitted)); United States v. Johnstone, 107 F.3d 200, 209 (3d Cir. 1997) ("Knowledge and intent may be inferred from all the surrounding circumstances ... [including] all the natural and probable consequences of an act knowingly done.").

In the context of the Anti-Kickback Statute specifically, the *mens rea* element requires proof that the defendants *knew* that the specific actions they took were illegal. *See United States ex rel. Hart v. McKesson Corp.*, 96 F.4th 145, 157 (2d Cir. 2024), *cert. denied*, 145 S. Ct. 163 (2024) ("[T]he defendant must act with knowledge that his conduct was unlawful." (internal quotation marks omitted)); *Pfizer, Inc. v. United States*, 42 F.4th 67, 77 (2d Cir. 2022); *United* 

States v. McClatchey, 217 F.3d 823, 829 (10th Cir. 2000); United States ex rel. Langer v. Zimmer Biomet Holdings, Inc., 743 F. Supp. 3d 282, 292 (D. Mass. 2024) ("To establish a knowing and willful violation, Relator's complaint must allege that Zimmer acted with knowledge that its conduct was unlawful."). The AKS also imposes the requirement that the defendant intended through the conduct at issue to induce sales of products. Knowledge that sales might result, or even evidence that a defendant "hoped or expected or believed that" a purchase would result from the payment does not equate to an intention to induce a purchase. *United States v. Regeneron Pharms.*, Inc., No. CV 20-11217-FDS, 2020 WL 7130004, at \*8 (D. Mass. Dec. 4, 2020) (quoting McClatchey, 217 F.3d at 834). Rather, to be illegal under the Anti-Kickback Statute, inducement of a purchase must be "the 'motivating factor" for the remuneration. *Id.* (quoting McClatchey, 217 F.3d at 835 n.7); see also United States v. Teva Pharms. USA, Inc., 560 F. Supp. 3d 412, 420 (D. Mass. 2021) (holding that under AKS, "liability attaches only when the statements and actions of a [defendant] reveal an intent beyond a 'collateral hope or expectation,' such that it is clear that the remunerations were designed specifically to encourage claims to Medicare." (internal citation omitted) (quoting McClatchey, 217 F.3d at 834 n.7)).

The Superseding Indictment alleges that the consulting program was a "sham" and "designed" for bribes. These express allegations of willfulness and conspiratorial intent relate to the *mens rea* elements. As a fundamental matter, Dr. Chin is entitled to rebut these accusations and anticipated testimony by government witnesses, including on *mens rea* issues. Potential defense strategies focus on knowledge and intent here, including through a look at the limited amount of consulting payments at issue compared to the value of benefits and improvements in the innovation of products and patient care. A jury could find that the purposes of obtaining feedback from consultants, innovation, and quality of patient care formed the purposes of the consulting program

and payments. Given issues of witness credibility and the importance of *mens rea* requirements for the crimes charged, Dr. Chin should be permitted to elicit testimony addressing positive circumstances surrounding the consulting program.

Furthermore, the language in the Superseding Indictment and reports produced by the government suggest that one or more of its witnesses may testify that the consulting program was a "sham" or the like, and that it incentivized one surgeon to conduct unnecessary procedures or use more products for monetary reasons. Such information may be relevant only to the extent sufficiently linked to Dr. Chin's understanding about a bad purpose for the consulting arrangement. To the extent that Dr. Chin had reasons to believe instead that the consulting program developed innovation and helped patients, such information tends to show a lack of the culpable *mens rea* that the government must prove.

The cases on which the government relies do not support the broad preclusion ruling that it seeks. Most of the cases merely stand for the proposition that the government need not prove harm to patients or a lack of necessity for medical services as essential elements of the charged offenses. In the first case on which the government relies, *United States v. Bay State Ambulance & Hospital Rental Service, Inc.*, 874 F.2d 20 (1st Cir. 1989), the court addressed a Medicare fraud provision and assessed whether a jury instruction that expressly required the government to prove "corrupt intent" sufficed without giving an instruction, which the defense had requested, stating that the reasonableness of payments could provide a defense. Contrary to the government's approach in the present motion, the First Circuit ruled that "the circumstances surrounding the conduct and statements were relevant." *Id.* at 33. As in *Bay State Ambulance, mens rea* for a specific-intent offense is at issue here. There the court reasoned that the jury found the defendant "not guilty on all but one check payment," which reflected that it "could have believed that the

check payments were compensation for work done with only an incidental improper purpose" and therefore acquitted on those charges, while finding the delivery of two cars to have an improper purpose. *Id.* at 30. In other words, by focusing on how surrounding circumstances reflected genuine value, the *Bay State Ambulance* decision refutes, rather than supports, the government's present position.

Other case law on which the government relies is equally unhelpful to its position. The government next cites, for example, to this Court's decision in *United States ex rel. Bawduniak v. Biogen Idec, Inc.*, No. 12-CV-10601-IT, 2018 WL 1996829 (D. Mass. Apr. 27, 2018). In *Biogen Idec*, the Court addressed a motion to dismiss under Fed. R. Civ. P. 12(b)(6) and found that a relator need not allege that a specific *quid pro quo* "changed prescribing habits" in exchange for a payment. *Id.* at \*3. Nothing in this Court's *Biogen Idec* decision remotely addressed the scope of evidence with which a defendant can attack express accusations or the credibility of witnesses, or how a defendant can rebut proof of *mens rea* or conspiratorial intent to induce purchases. Indeed, exposure to good results from consulting payments would be a fact from which a jury could infer that a defendant acted with proper purposes and lacked the requisite *mens rea* that the government must establish as criminal, including either a willful violation of the AKS or a conspiratorial intent to commit such an unlawful act.

The government relies on another civil case, *United States ex rel. Witkin v. Medtronic, Inc.*, No. 1:11-CV-10790-IT, 2024 WL 1892405, at \*15 (D. Mass. Mar. 31, 2024), which arose in the context of summary judgment standards. In *Medtronic*, this Court explained the right of even civil defendants to present expert testimony and surrounding circumstances to impeach the credibility of witnesses and establish the fair value of payments, which could also bear on willfulness and conspiratorial intent issues here:

To the extent Medtronic attempts to question McNamara's credibility generally and offers an expert who reaches a different conclusion, that is a determination for the trier of fact, not the court. "So long as an expert's scientific testimony rests upon good grounds, based on what is known, it should be tested by the adversarial process, rather than excluded for fear that jurors will not be able to handle the scientific complexities." *Milward v. Acuity Specialty Prod. Grp., Inc.*, 639 F.3d 11, 15 (1st Cir. 2011) (internal quotation marks and citation omitted). "Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence." *Id.* (quoting *Daubert v. Merrell Dow. Pharm., Inc.*, 509 U.S. 579, 596 (1993)). Thus, because resolution of this fair-market-value dispute would require the court to choose between the well-grounded opinions of competing experts, summary judgment is inappropriate on the issue.

*Id.* at \*15.

The government also relies on *Pfizer, Inc v. United States Department of Health & Human* Services, 42 F.4th 67 (2d Cir. 2022), in which Pfizer challenged an advisory opinion issued by the Department of Health and Human Services prior to the deregulatory impact of Loper Bright Enterprises v. Raimondo, 603 U.S. 369 (2024). As in the Biogen Idec case, nothing in Pfizer remotely addresses the admissibility of evidence concerning surrounding circumstances as part of defending against criminal charges that require proof of heightened mens rea and conspiratorial intent to achieve an unlawful purpose. Indeed, the Pfizer decision reaffirms that substantive offenses under the Anti-Kickback Statute contain essential elements of specific intent for a quid pro quo. Pfizer, Inc., 42 F.4th at 72, 79 (holding that, under the Anti-Kickback Statute, one factor cutting against "[o]vercriminalization" is the requirement that "a person must 'knowingly and willfully' provide prohibited remuneration to be liable, which means she must have offered the payment with the intent to violate a known legal duty"). The same problems arise with the government's invocation of Pharmaceutical Coalition for Patient Access v. United States, 126 F.4th 947, 962 (4th Cir. 2025), which involved a challenge to HHS's advisory opinion, again without remotely addressing evidentiary issues concerning a criminal defendant's right to

challenge express accusations in an indictment or to attack the credibility of witnesses, or to rebut evidence of *mens rea* for the substantive offense or the corrupt intent of a conspiratorial agreement.

The criminal cases from other circuits on which the government relies also provide no help to its position. In *United States v. Patel*, 778 F.3d 607 (7th Cir. 2015), the court merely addressed the sufficiency of evidence to support a conviction, not the scope of admissible evidence with which to attack the credibility of witnesses or to rebut a finding of mens rea on the substantive offenses or conspiratorial intent to commit an unlawful act. Id. at 619 (focusing on whether a "reasonable factfinder could conclude that Patel 'willfully and knowingly' received a kickback"). In another decision on which the government relies that addressed a pertinent evidentiary ruling, the court merely prevented a trial within a trial concerning medical necessity, while allowing evidence about helping patients and the absence of any request that a provider do anything improper. See United States v. Eggleston, 823 F. App'x 340, 343 (6th Cir. 2020). In fact, the Eggleston court held that a defendant could resort to evidence of good treatment for "any other reason" than to argue medical necessity. Id. ("Eggleston's cross-examinations of [government witnesses included ... h]er attorney ask[ing] about the treatment [patient] Hodge received and whether it helped her [and] Hodge confirmed that it did help," and patient "Jones was likewise asked about his treatment and whether Eggleston ever asked him to do anything improper [and] Jones confirmed that Eggleston did not") (citations to record omitted)).

Simply put, the government has failed to justify the categorical preclusion of defense evidence and argument on which a jury could rely to conclude that the consulting program was not a sham, or with which a jury could assess credibility of government witnesses, or consider whether Dr. Chin acted willfully or with conspiratorial intent to violate the law by inducing purchases rather than to innovate and improve patient care through the use of consultants. At the very least, the

Court should await trial before considering a categorical preclusion of evidence and argument about impact on patients or Dr. Chin's perception of such impact. Any contours of proof or jury instructions concerning these matters can be assessed best on an evidentiary record and with specific proffers of evidence at trial. Until then, there should be no categorical bar on Dr. Chin's efforts to show reasons he believed in the proper purposes and benefits of the consulting program and to show the lack of criminal or conspiratorial intent on his part or on the part of any other potential co-conspirator. The government's motion should be denied.

#### Conclusion

Based on the foregoing, Dr. Chin respectfully requests that the Court deny the government's motion *in limine* to preclude evidence or argument concerning medical necessity or lack of patient harm.

Respectfully submitted,

### **KINGSLEY CHIN**

By his attorneys,

/s/ Joshua L. Solomon

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# **CERTIFICATE OF SERVICE**

The undersigned certifies that this document, filed on May 2, 2025, through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing.

/s/ Joshua L. Solomon